

February 18, 2015

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[Delayed] Approval of a premarket notification 510(k) of wound healing material (TDM-511) in the US

(This original disclosure in Japanese was released on February 16, 2014 at 20:30 (GMT+9))

We hereby announce that, on February 13, 2015 (US time), 3-D Matrix, Inc., our subsidiary in the US, obtained a premarket notification 510(k) approval of the wound healing material (development code: TDM-511) from FDA which has been announced to submit as of October 23, 2014.

The premarket notification 510(k) which 3-D Matrix, Inc. made a submission of is one of the medical device reviews by FDA. Since the substantial equivalence between TDM-511 and previously approved wound healing materials in the US was admitted by FDA, 510(k) approval for TDM-511 was obtained.

This approved product is applied to cover injured skin (epidermis, epidermis/dermis) with gel formed by nanofibers produced by self-assembly. The product provides a moist wound and the regenerating environment for injured skin tissues which results in acceleration of wound healing and assurance of aesthetic effect on the regenerated part (minimization of scar). This non-animal/plant derived product does not have antiseptics at risk of allergic reaction or skin irritancy.

This product can be used as Rx (prescription) for injuries of skin from epidermis to dermic layer (pressure sore, leg ulcer, diabetic ulcer, surgical scar) under supervision of a health care professional and also be used for minor cuts, minor abrasions, minor wounds and minor burns(1st degree burns) as OTC.

Our group starts to make an entry into the field of skin regeneration by starting with the indication for treatment of skin injuries (e.g. burn, pressure ulcer) and then plan to gradually expand the indications to cosmetic surgery (e.g. hyaluronic acid injection) and skin cancer treatment by mixing this product and anticancer drugs.

The influence of this approval has not been considered in the company's earning forecast for the full year and the current Mid-term Business Plan. However, we will make necessary announcements when it is deemed that there is any influence.